Downstream Users of Chemicals Co-ordination group

DUCC/CEFIC pilot project on Exposure Scenarios and communication in the supply chain

Formulators phase: testing the SUMI selection approach ENES action 4.1. – Report

ENES
EXCHANGE NETWORK ON EXPOSURE SCENARIOS

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DUCC

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Introduction

The main objective of this phase of the "Pilot project on exposure scenarios and communication in the supply chain" was to collect experience from formulators on processing the exposure scenarios (ESs) received in order to generate safe use information for a mixture by selecting the appropriate **SUMIs – Safe Use of Mixtures Information**.

The SUMI is a template developed by DUCC – the Downstream Users of Chemicals Coordination Group, to help formulators in fulfilling their duties under REACH with regards to safe use communication down the supply chain to customers via their product Safety Data Sheets (SDS).

The SUMIs are directly correlated to the **SWEDs** – Sector-specific Workers Exposure Descriptions, which provide the information on use conditions for upstream communication. The SWEDs are one of the elements of the use maps package.

When the registrant uses the SWEDs for their workers' exposure assessment under REACH, a corresponding SUMI will be available for the formulator to forward to his end-users, provided that the conditions described in the correlated SWEDs are met – e.g. ventilation conditions, etc.

Some of the DUCC members have prepared SUMIs for the most relevant uses within their sector. The SUMIs are a 2-page document with simple and clear instructions, summarising the relevant safe use information to the users of the products, in a standardised way. Additionally, to visualize the conditions of safe use (e.g. use of gloves, respiratory protection) DUCC developed some pictograms [1].

Under ENES action 2.4 (lead by CEFIC), several exposure scenarios were generated on the basis of sector use maps and on the basis of GES and made available to support the proposed testing for the formulators phase. The following situations have been identified as relevant for collecting further experience from companies when generating safe use information for the mixture, including selecting the adequate SUMI:

1. Exposure scenarios for the substances in the mixture are derived from sector use maps – "Homogeneous case"
1. Exposure scenarios for the substances in the mixture are derived both from sector use maps and ESIG Generic Exposure Scenarios (called GES) – "Heterogeneous case"

The suggestions included in this report result directly from the observations received from the testers and were discussed at the ENES technical workshop on 3-4 September 2019. The outcome of this project provided input to the REACH Review action 3 – aiming at improving the quality of Extended Safety Data Sheets.[2]

Brief description of the tasks

Volunteering companies were assigned 2 to 3 simple mixtures (2 to 3 classified components per mixture maximum). For each mixture they were asked to derive safe use information for their customers.

[1] Available on the DUCC website, section Publications/Guidance & Tools

[2] More information can be found on the background documents for the second workshop on RRA 3.

As an **input** volunteering companies received:

- the details on the mixture composition (substances and concentration) [3]
- the description of the use of the mixture
- the mixture SDS with ESs annexed for each classified substance in the mixture [4]
- the SUMIs and the specific instructions developed by sectors (A.I.S.E., CEPE, EFCC and FEICA) to support them in applying the SUMI selection method

As an **output**, companies were asked to:

- provide the derived safe use information for mixtures they would communicate to their customers for the mixtures assigned
- fill in a short feedback form to report any difficulty they may have encountered in following the instructions for selection of the relevant SUMIs or any improvement needs they would have identified

Timing and participants

This exercise ran between March and April 2019. In the following table the final number of testers is presented for each sector:

Sector	Number of feedback forms received
A.I.S.E. **Detergents and Maintenance products**	10
CEPE **Paints and Coatings**	11
EFCC **Construction Chemicals**	3
FEICA **Adhesives and Sealants**	12
TOTAL	**35**

[3] To be selected by A.I.S.E., EFCC and FEICA

[4] The exposure scenarios received will have been generated based on use maps from A.I.S.E., EFCC and FEICA and/or GESs from ESIG, as part of the Cefic Pilot II on ESs and communication in the supply chain – ENES action 2.4

Feedback

General comments

- The SWED/SUMI approach was generally understood;
- The application of use maps concept (with standardised uses for each sector, with codes for the different contributing activities) is easy, quick and straightforward if the person is familiar with it;
- In most cases the exercise was complete, i.e. it was possible to identify a SUMI that correctly describes the conditions of use to be communicated downstream / uses of the mixture;
- Heterogeneous case is more difficult/burdensome than homogeneous case (in one sector the SUMI could not be identified/validated);
- There were some difficulties in performing the exercise when the SWED code was not indicated consistently throughout the document (e.g. no reference to the A.I.S.E. SWED code in the contributing scenarios themselves, only in the overview table)

Time for whole exercise and time driving factors

In the feedback forms, testers reported having spent between 1 hour and more than one day to apply the SUMI selection methodology and select the relevant SUMIs for the mixtures designed by the sectors – further detail is provided in the second table below.

The time reported included the time required to get familiar with the method in general (most testers applied the method for the first time), and the time required to get familiar with the testing material provided.

A.I.S.E.	CEPE	FEICA	EFCC
2.5 h (average)	1h – ≥ 1 day	2.5h – 4h[1]	1.5 h – 2.5 h [5] [6]

During this exercise, some differences between sectors have been identified. Some reasons could be provided for that:

- For the CEPE testing, the exposure scenarios were not based on CEPE use maps;
- In the case of FEICA, individual checks of the exposure scenario conditions were performed[7];
- For CEPE and EFCC not all volunteers have followed the instructions;
- differences in the instructions and complexity of the test cases that were provided by the sectors.

Testers were asked to specify how much time was required to apply each step of the method and to report possible difficulties encountered at each step. The table below summarises the key elements reported, for each step:

[5] The different individual OCs/RMMs were checked for the different SWEDs and ESs, which increased the overall time.
[6] Average time taken, except when instructions were not followed.
[7] The use-identification took 30 minutes in average. However, for internal purposes, the different individual OCs/RMMs were checked for the different SWEDs and ESs, which increased the overall time. This step is *not* needed in the SUMI approach.

Step	Time taken[8]	Comments
1 **Identifying the uses/ contributing activity in the sector use map**	5-40 min	- Possible for most testers - Easy task for vast majority of testers - Uses generally correctly identified by the testers
2 **Identifying relevant ES / [use(s) and contributing activities] in ext-SDS** **+** **check for SWEDs**	10 - 120 min	- At least one ES was found by most testers, even all of them in some sectors, but not always easily [9] - Useful to have use code in the exposure scenario
3 **Comparing conditions of use/SWEDs from different Exposure Scenarios [10]**	Up to 4h	- relatively easy if relevant information (i.e. OCs/RMMS) is available - burdensome/time consuming if relevant information is missing
4 **Identify appropriate SUMI**		– For the homogeneous case, this may become difficult if the SWED code is not indicated consistently throughout the document – For the heterogeneous case, it is difficult to conclude on safe use when conditions in the received ES don't match with those in the sector SWEDs/SUMIs – sometimes different SUMIs were chosen for the same scenario by different testers [11] – For CEPE, the OCs and RMMs needed (i.e. included in the incoming ES) were stricter than the ones in the CEPE SUMIs

[8] This represents the minimum and maximum time that the task took for all sectors.

[9] For CEPE: this task was not straightforward since the ES used in this pilot were not based on the CEPE use maps. In some cases, it was possible to find an ES that covered the use of the sector, but all content of that ES had to be checked.

[10] This task is always needed in the heterogeneous case. For the homogeneous case, the task was also performed by one sector, for other purposes.

[11] The project team believes that this was due to some misunderstanding, therefore one of the conclusions of this project is that more guidance/clarification is needed. Please refer to the related part of this document for more details.

What worked well what could be improved

		
EXPOSURE SCENARIO	<u>Format/Template</u> - Appreciation of "harmonized" (Chesar) template + Table of Contents - ToC positive/helpful aspects: if hyperlinks are provided <u>Content</u> - Very clear and complete which is not always the case in "real life"	<u>ToC</u> - Could include additional information: e.g. use code - Could be improved to make it easier to read and distinguish individual ES <u>Title</u> - In some cases, the title was too generic: "Various products; Various sectors". The result was that for one sector, respondents were not always able to distinguish if an ES was coming from GES or a sector use map. <u>Format/Template</u> - Use code is not mentioned - SWED codes not being mentioned consistently throughout the document. No reference to the SWED code in the CS themselves, only in the overview table. <u>Content</u> - Some of the ESs received from different suppliers had differences in some parameters (concentration, OC/RMM, SWED covered)
USE MAP / SWED	<u>Homogeneous case</u> - Identification of uses in the Use Maps is straightforward - Identification of SWED code in the ES is straightforward	<u>Heterogeneous case</u> - Comparison of conditions of use between ES and SWED/SUMI is more complicated when compared with the "simple" identification of the SWED code in the homogeneous case <u>General comment</u> - Concept would be very helpful when implemented broadly. ESs are currently often not generated based on Use maps (and therefore they don't contain a SWED code)
SUMIS	- Very user-friendly	- Lack of clarity on how to choose the SUMI considering the product's hazard/classification

		
GES	- Indication of ESVOC SpERC code in the ES helpful as it allowed to conclude that the ES was based on GES - The GES/Sector use map mapping table is useful	<u>ToC</u> - Not known to most of the participants <u>Title + OC + other info</u> - Not tailored made to sectors <u>PROCs/OCs</u> - Don't match with those from sectors <u>Content of ES</u> - Needs to be checked in detail, like a standard DU compliance check / simplification brought to formulators of end-use mixtures by use maps/SWEDs concept is lost - The safe use information for mixtures will need to be derived individually for the ESs based on GES - If to be used in certain sectors, they would choose to work with suppliers for making them move to SWEDs approach - No possibility to use sector SUMIs because there is no SWED assigned - For some sectors, the conditions were sometimes inconsistent with reality (e.g. outdoor in PROC 8a)
OTHER SPECIFIC COMMENTS	<u>CEPE approach</u> - the titles of ES that were based on GES were clearer[12]	<u>CEPE approach</u> - Some relevant Phys-Chem information missing or not directly usable (MW, vapour pressure)

Case of different suppliers for the same substance

Differences between the exposure scenarios received were observed, both in the homogeneous and heterogeneous case.

One reason cited for the heterogeneous case is the different sources (use maps and GES)[13]. Another reason, not mentioned by the testers, but confirmed by the project team is that sometimes registrants have deviated from the use maps/SWED input.

Examples of differences include concentration, OC/RMM and SWED covered.

[12] The most probable reason behind this comment is since the ES used in the CEPE exercise were not based on the CEPE use maps. In other words, the titles of the ES based on the GES were clearer to CEPE because the other ES were based on other sectors' use maps and, therefore, not reflecting the uses of CEPE.

[13] Chapters 2.6 and 3.6. from the registrants' phase report provide more details on the differences between GES and use maps.

Feedback from customers on SUMIs

	
A.I.S.E.	
- clear and user-friendly - request for inclusion of CLP classification – not possible because SUMIs related to use (not product specific) - smart tool	- more practice needed
CEPE (previous consultation/testers' views)	
- adequate - sufficient - nice way of presenting information - good overview of information required for a number of stages	- Process description and RMM advice needs to be clearer/less vague → in the meantime process descriptions were updated; reference to SDS section 8 for the RMMs
General comments	
- the value of providing the information in a clear format, with simple language and pictograms so as to facilitate people creating workplace instructions.	
Comment particularly addressing the similarity of a REACH CSA output and an OSH workplace risk assessment, in terms of risk management advise for workers	
- Information in SUMI is no more than needed for CAD; duplication with no added value for DU - very generic; would be met by the output of the Chemical Agents Directive risk assessment for the use of the mixture and could mostly be drawn from the main body of the SDS related to personal protection.	

Some misunderstandings in the application of the approach and on the target audience of the SUMIs

- The activities not covered in the ES received, i.e. that were missing, were identified by most participants, but some still selected the SUMI for that(those) activity(activities) to be attached to the mixture SDS

  → incorrect application of the approach: the result of the approach is that one or few SUMIs are identified as covering all the conditions of use from the ES received and relevant for the mixture produced. A SUMI cannot be attached to the mixture SDS if the respective use is not covered in any of the ES received.

- When trying to identify the relevant ES for the use in question, is not necessary to compare the SWEDs contents to the ES contents, comparison of use titles should be enough

→ the conformity check by the formulator is a stepwise approach. The first step is to check the use titles. The SWEDs, i.e. the OCs/RMMS of the different contributing activities, are only to be checked as a second step, for the uses chosen on the first step.

- The SUMIs' recipients are end-users of chemicals, not the registrants (who will use the SWEDs instead). The SUMIs include information, some already included in the main body of the SDS, to explain how the products can be used safely, in a language easy to understand. The information in the SUMI can also provide support to the workplace safety assessment.

Suggestions for improvement

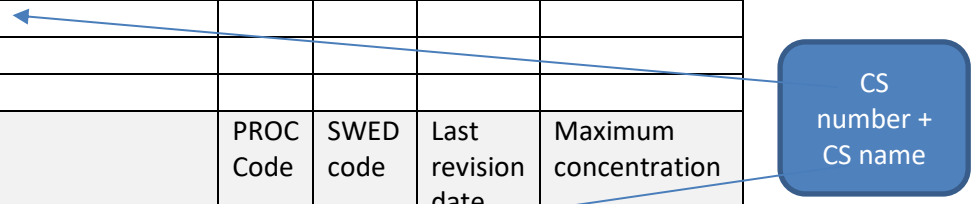
Improve navigation through the exposure scenario annex

- Improve the **Table of Contents** (ToC) of the SDS Annex:
    - Add use code (from use map)[14]

      (so that recipients of the ESs can identify on which basis the assessment has been done by registrants, and can more easily identify the use relevant to him)
    - Include hyperlinks to the ES itself
- Improve **the title section of each ES:**
    - Add use code (from use map)
    - Always provide SWED code for the contributing scenarios, if the conditions of use from the SWEDs are not modified
    - Include the "last revision date" for each exposure assessment input (SWED, SpERC)
    - Consider including concentration into the overview table in the ES title section

Example on how the **title section** of each exposure scenario could be improved:

ES / Use name				
Environment	ERC Code	SpERC code	Last revision date	M-safe
1.				
2.				
3.				
(…)				
Worker	PROC Code	SWED code	Last revision date	Maximum concentration
1.				
2.				
3.				
(…)				



Obs: example for a professional use

Minimise the efforts for comparing Exposure Scenarios/Contributing Scenarios across suppliers and across substances

- Include SWED reference into the ES to limit comparison of OC/RMM to spot-checks only
- Don't include the SWED code in the ES if the assessor has deviated from the OCs/RMMs in the SWED/use maps

[14] To note that the use code will include the name of the sector, therefore facilitating the identification of the uses by the formulator.

It is important to note that one of the features of the SWED/SUMI approach is that the SWED code will be provided in the exposure scenario, to allow an easy identification of the use/contributing activity in question by the formulator who receives the exposure scenario as well as a confirmation that the OC/RMM described in the use maps and in the SUMI have been used for the assessment.

In Chesar, the SWED code from the use maps is communicated in the exposure scenario if the risk assessor has kept the input parameters from the use maps. On the contrary, if the risk assessor changed the input parameters included in the SWED, the code is not communicated in the exposure scenario.

Clarify the SUMI selection methodology

- How does the mixture classification (for local effects) impacts on the SUMI selection? [15]
- How to select the right SUMI when the required risk management levels across the substances in the mixture (at the concentration required for the technical performance) are different?

Increase understanding on correspondence between GES and downstream sector use maps

- Increase understanding on correspondence of GES and sector use maps/contributing activities; include explanations into the sector guidance; mention link to ESIG GES mapping table → this is already being considered by some DUCC sectors
- For ESs generated with GES: include sector in the ES title (sometimes the name of the GES is too generic). This would require e.g. use codes for GES.

Improve explanation and guidance; add examples

- The use maps (including SWED and SUMI) concept/approach needs further explanation for beginners (registrants, new-coming sectors, formulators, end-users)
- Clarify with registrants that the SWED code can only be included in the ES if nothing has been changed, i.e. the OCs/RMMs in the SWEDs were not changed when doing the risk assessment
- Clarify with formulators that if the SWED code is included in the ES it means that the SWEDs have been used for the risk assessment, without changing any input parameter
- Clarify with formulators that if the SWED code is <u>not</u> included in the ES it means that the conditions in the SWEDs have been changed by the risk assessor and therefore a detailed check of the OCs/RMMs is needed.
- Sectors could engage with their customers (this can include e.g. training)
- For some sectors, environmental considerations to be considered (and link with SpERCs explained) → this is in progress
- Group/define common RMMs for similar CSs within sectors (e.g. spraying versus brushing)

[15] Although primarily this feedback was raised by testers of the A.I.S.E. test case, and the sector recognises the value of improving guidance in relation to this topic, this comment can be considered as a point to be clarified via further guidance for all sectors involved in the pilot. However, it is also to note, that the comment received during the pilot resulted from a lack of understanding of the instructions and the way the pilot project was designed – not designed to cover all parameters of real life.

Specific comments received on the CEPE approach

Some testers have suggested the following topics that could deserve further clarification of the CEPE approach:

- how to use toxicological data from ECHA website (e.g. which DNEL) [16]
- provide conversion tools for certain phys-chem properties
- what to do when a SWED cannot be validated.

These comments relate mainly to the quantitative validation method included in CEPE's approach (in addition to qualitative checking of the OCs/RMMs in received ESs against those in the SWED/SUMI, where a CEPE SWED code is not provided in the ES).

This quantitative method defines the applicability domain of the CEPE SUMIs, by calculating the expected exposures for each SWED and thereby defining a 'minimum tolerable DNEL' for safe use (i.e. giving an RCR <1). Formulators can compare the DNELs of (relevant) substances in their mixture against this value and derive an RCR: if <1 the use is deemed to be safe and the SUMI can be selected.

When a SWED cannot be validated – by the quantitative method above and/or by qualitative checking of OCs/RMMs – a formulator needs to take further action, e.g. by adapting the SWED conditions to reflect specific use conditions. This is outside the scope of this pilot. CEPE is developing supplementary guidance for members on next steps that formulators can take in such cases.

[16] This is also relevant, more in general, in case a DU wants to perform a DU CSA using the use maps parameters.

Annex I – Additional information provided to the testers as an introduction to the exercise

Pilot Project on ESs and communication in the supply chain
Formulator step: testing SUMI selection approach

— ENES Action 4.1. lead by DUCC —

Organisation of the DUCC SUMI pilot project

Participants

This project is organised in the following way:

Lead: DUCC (Laura Portugal)

Core Group (in charge of the organisation of the pilot): Alejandro Garabatos (Cefic), Cornelia Tietz (ESIG), Divina Gomez (FEICA), Martin Glöckner and Sophie Dikoundou Njooh (EFCC), Giulia Sebastio (A.I.S.E.), Jan Robinson (CEPE), Evelyn Tjoe Nij (Cefic), Gerald Bachler (Consultant representing Concawe), Laure Anne Carton (ECHA), Andreas Ahrens (ECHA).

Participants: Formulators who have replied to the call for volunteer launched during summer 2018 by Cefic (ENES action 2.4) and formulators that will apply to this call for participation.

Timing

What	Who	When
Expression of interest by participants	Volunteers	By 22 March
Kick-off webex meeting with the formulators • explain the tasks to be carried out, mixtures and exposure scenarios to be used • fix deadline to carry out exercises	Formulators	Between 5 and 17 April
Testing exercise	Formulators	Until mid-May 2019
Webex for debriefing with Formulators	Core group / Formulators	2nd week of June
Preparation of a report	Core group	September

Annex II – Acronyms

A.I.S.E.	International Association for Soaps, Detergents and Maintenance Products
CAD	Chemical Agents Directive
Cefic	The European Chemical Industry Council
CEPE	European Council of the Paint, Printing Ink and Artists' Colors Industry
Chesar	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging of substances and mixtures Regulation (EC) No 1272/2008
CS	Contributing Scenario
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No-Effect Level
DUCC	Downstream Users of Chemicals Co-ordination group
ECHA	European Chemicals Agency
EFCC	The European Federation for Construction Chemicals
ENES	Exchange Network on Exposure Scenarios
ERC	Environmental Release Category
ES	Exposure Scenario
ESIG	European Solvents Industry Group
FEICA	Association of European Adhesive and Sealant Industry
GES	Generic Exposure Scenarios
MW	Molecular Weight
OSH	Occupational Safety and Health
OC	Operational Conditions
PROC	Process Category
RCR	Rick Characterisation Ratio
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (EC) No 1907/2006
RMM	Risk Management Measures
SDS	Safety Data Sheet
SpERCs	Specific Environmental Release Categories
SUMI	Safe Use of Mixtures Information
SWED	Sector-specific Workers Exposure Description
ToC	Table of Contents